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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/466,778	12/20/1999	GREGG A. HASTINGS	PF487	1584

22195 7590 04/09/2004

HUMAN GENOME SCIENCES INC  
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EXAMINER

MITRA, RITA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/466,778	HASTINGS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rita Mitra	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-66,68-75 and 77-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-26,31-35,41-47 and 55-80 is/are allowed.
- 6) ☒ Claim(s) 27-30,36-40,48-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Status of the Claims***

Applicants' amendment in response to office action dated April 9, 2003 filed on August 8, 2003 is acknowledged. Exhibits A-D attached to the 'Amendment and Response' are acknowledged. Claims 31, 32, 36, 37, 41-44, 48-51, 55-66, 68-75 and 77-80 have been amended and entered. Claims 67 and 76 have been canceled. Therefore, claims 23-66, 68-75 and 77-80 are currently pending and are under examination.

### ***Response to Remarks and arguments***

#### **Rejections under 35 USC § 101**

The rejection of claims 23-66, 68-75 and 77-80 under 35 USC § 101, is withdrawn in view of amendment to claims 31-32, 36-37, 41-44, 48-51, 55-68, 72-77; providing Exhibits A-D and IDS reference AI, AG, AJ; and Remarks on PP 14-17.

#### **Rejections under 35 USC § 112, First Paragraph**

The rejection of claims 23-66, 68-75 and 77-80 under 35 USC § 112, First Paragraph, is withdrawn in view of amendment to claims 31-32, 36-37, 41-44, 48-51, 55-68, 72-77; providing Exhibits A-D and IDS reference AI, AG, AJ; and Remarks on PP 14-17.

#### **New Ground of Rejection**

##### ***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-30, 36-40 and 48-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification at page 7 is objected to because the biological material used in the claimed process is a microorganism clone, which has been deposited with American Type Culture Association and has the accession number ATCC 203502. Since the clone is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the organism is not so obtainable or available, the requirement of 35 U.S.C. 112 may be satisfied by a deposit of the microorganism.

The specification fails to disclose that the deposit was made under the terms of Budapest Treaty on the international recognition of the deposit of microorganisms for purposes of patent procedure. However Applicants fail to provide a receipt for the certificate of deposit. It is apparent that the claimed deposit material is essential to the claimed invention and the deposit is necessary for an adequate written description and enablement for the claimed invention. Applicants should provide a photocopy of the receipt of the certificate of deposit along with a declaration stating that it has been deposited under the terms of Budapest Treaty. The Office notes that during the pendency of this application, access to the invention will be afforded to the Commissioner upon request where all restrictions upon availability to the public will be irrevocably removed upon granting of the patent and that the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer where the deposit will be replaced if it should ever become inviable.

That the applicants have apparently incorporated specific references into the specification does not eliminate the issue of public availability and permanence as the vectors cited in the references and the references per se do not indicate, public availability of the starting materials in as much as the biological materials mentioned in a publication may be proprietary and not publicly available.

It is apparent that the claimed clone is essential to the claimed invention and the deposit is necessary for an adequate written description, enablement, and best mode for the claimed

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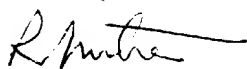
invention, because the specification lacks a specific description or demonstration of hundred percent reproducibility of the claimed protein from the deposit. Because of the overlapping sequences the deposit is not 100% reproducible. Specification indicates at page 27, 44, 64 and 67 that protein has been isolated from the ATCC 203502 clone, however, specification only gives a generic description of isolation of a selected clone from the deposited sample, it fails to demonstrate the selection of a single clone from the mixture of cDNA clones from the deposit. Thus, the specification does not disclose a repeatable process to obtain the claimed clone from the deposit.

### *Conclusion*

Claims 27-30, 36-40 and 48-54 are rejected. Claims 23-26, 31-35, 41-47, 55-80 are allowable.

### *Inquiries*

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (571) 272-0951. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547



Rita Mitra, Ph.D.

April 3, 2004

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